UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

CHURCH & DWIGHT CO., INC.,

Plaintiff,

–v–

SPD SWISS PRECISION DIAGNOSTICS, GMBH,

Defendant.

14-CV-585 (AJN)

MEMORANDUM AND ORDER

ALISON J. NATHAN, District Judge:

On July 1, 2015, this Court issued an Opinion and Order finding, *inter alia*, that Defendant SPD Swiss Precision Diagnostics, GmbH ("SPD") had engaged in false advertising under the Lanham Act and indicating it would enter a permanent injunction at a later date. Dkt. No. 397 ("July 1 Opinion"). On July 10, 2015, the Court received from SPD a motion to stay or modify any future injunction pending appeal. Dkt. No. 399. For the reasons explained below, the Court DENIES SPD's motion and enters its permanent injunction order simultaneously with this Memorandum and Order.

I. BACKGROUND

In 2014, C&D filed a complaint against SPD alleging false advertising of the Clearblue Advanced Pregnancy Test with Weeks Estimator (the "Product"). Dkt. No. 2. Pursuant to the parties' request, the Court agreed to bifurcate the issues of liability and damages. Dkt. No. 42. After an eight-day bench trial on liability, the Court found that "SPD's advertising conveys the false message that the product provides an estimate of weeks that is consistent with a doctor's estimate of weeks pregnant." July 1 Opinion at 27. The Court further found that the false

advertising was the result of "intentional deception." *Id.* at 1. As a result, the Court ordered both parties to meet and confer to try to reach an agreement on the specific language of a permanent injunction order. *Id.* at 49. In the event that the parties could not agree, the Court ordered each party to submit a letter setting forth its positions on the wording of a permanent injunction. *Id.* at 50-51. At a minimum, the Court suggested that any injunction would require SPD to recall the Product currently on store shelves and begin a corrective advertising campaign. *Id.* at 50. In anticipation of its eventual appeal, SPD filed a motion to stay or modify the injunction pending appeal on July 10, 2015. Dkt. No. 398. SPD filed its actual Notice of Appeal on July 30, 2015. Dkt. No. 419.

II. MOTION TO STAY INJUNCTION

Rule 62(c) of the Federal Rules of Civil Procedure provides: "While an appeal is pending from an interlocutory order or final judgment that grants . . . an injunction, the [district] court may suspend [or] modify. . . an injunction on terms for bond or other terms that secure the opposing party's rights." A stay of injunction is an "intrusion into the ordinary processes of administration and judicial review, and accordingly is not a matter of right." *Nken v. Holder*, 556 U.S. 418, 427 (2009) (citation omitted). In deciding whether to grant a motion to stay an injunction pending appeal, a court should consider four factors:

> (1) whether the movant will suffer irreparable injury absent a stay, (2) whether a party will suffer substantial injury if a stay is issued, (3) whether the movant has demonstrated 'a substantial possibility, although less than a likelihood, of success' on appeal, and (4) the public interests that may be affected."

LaRouche v. Kezer, 20 F.3d 68, 72 (2d Cir. 1994) (quoting *Hirschfeld v. Bd. of Elections*, 984 F.2d 35, 39 (2d Cir. 1993)). Of these factors, irreparable injury and likelihood of success on the merits "are the most critical." *Nken*, 556 U.S. at 434. While the factors are evaluated on a "sliding scale" where "[t]he probability of success that must be demonstrated is inversely

proportional to the amount of irreparable injury plaintiff will suffer absent the stay," *Thapa v. Gonzales*, 460 F.3d 323, 334 (2d Cir. 2006), an applicant for a stay of an injunction pending appeal "must establish more than a 'mere possibility' *both* of irreparable injury absent a stay and of success on the merits of the appeal" to prevail. *Chevron Corp. v. Donziger*, 37 F. Supp. 3d 653, 657 (S.D.N.Y. 2014).

A. Irreparable Injury to SPD

Irreparable harm is "perhaps the single most important prerequisite" before a stay of a permanent injunction pending appeal can be issued. *Bell & Howell: Mamiya Co. v. Masel Supply Co. Corp.*, 719 F.2d 42, 45 (2d Cir. 1983). Irreparable harm justifying a stay of an injunction must be "actual and imminent" as opposed to "speculative" harm, *Dexter 345 Inc. v. Cuomo*, 663 F.3d 59, 63 (2d Cir. 2011), that "cannot be remedied" without a stay. *Grand River Enter. Six Nations, Ltd. v. Pryor*, 481 F.3d 60, 66 (2d Cir. 2007).

It is undeniable that the injunction will cause SPD some harm. SPD argues that "immediate implementation of an injunction will cause SPD to suffer millions of dollars in lost revenue and additional costs, erode consumer trust in the brand and damage SPD's business goodwill." SPD Br. at 9. The Court turns first to the monetary costs of complying with the injunction.

If the monetary cost of implementing an injunction, standing alone, were sufficient to justify a stay of injunction pending appeal, "stays pending appeal would become routine, conflicting with the rule that such relief should be 'extraordinary.'" *Nat. Res. Def. Council, Inc., v. U.S. Food and Drug Admin.*, 884 F. Supp. 2d 108, 124 (S.D.N.Y. 2012); *see also Graphic Commc'ns Union v. Chicago Tribune Co.*, 779 F.2d 13, 15 (7th Cir. 1985) ("[T]he fact that an order . . . imposes a cost . . . does not show irreparable harm. Otherwise every order . . . would

be deemed to create irreparable harm, and it would be easy to get such orders stayed."). Admittedly, the magnitude of the cost is undoubtedly a relevant factor in evaluating irreparable harm; here, the cost of the recall would be about $3.6 million. Zingg Decl. ¶ 5 (Dkt. No. 401). That cost is not insignificant. However, while SPD described this cost in detail, it made no effort to explain what consequences such an expenditure would have on the company. In essence, SPD lists costs and asserts they will cause "irreparable harm," but fails to explain why. This lack of explanation is particularly troubling because the Court clearly indicated that the question of an injunction should be addressed at trial. *See Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2014 WL 2526965, at *17 (S.D.N.Y. June 3, 2014) (ordering consolidation of C&D's motion for preliminary injunction with the trial on the merits). SPD presented no evidence of the effect of an injunction during the course of the trial and has failed to do so in the briefing here. Without evidence of the *effect* of the cost of complying with the injunction, SPD has established no record from which the Court could conclude that the enumerated monetary costs rise to the level of irreparable harm.

In addition to cost, SPD argues that the injunction, and particularly a recall, will cause loss of consumer trust and goodwill. As an initial note, the magnitude of such a loss is speculative. For example, SPD argues that "a recall would . . . damage SPD's reputation . . . with . . . health care providers," SPD Br. at 9, but provides no evidence that health care providers would change their views on the quality of the product based on a false advertising recall. Relatedly, SPD argues that consumers would view the product as unsafe or believe it was no longer approved by the FDA. *Id.* Again, there is little reason to believe consumers would react in this way. There is no such implication in this Court's July 1 Opinion, and SPD will certainly endeavor to communicate to customers that any recall has no bearing on safety. Further, if

consumer trust and goodwill are damaged, it is not necessarily a result of any injunction or recall, but because SPD engaged in "intentional deception of an egregious nature." July 1 Opinion at 1. In sum, SPD's alleged losses of consumer trust and goodwill are speculative and are attributable to SPD's underlying conduct as opposed to the injunction. As a result, these injuries do not rise to the level of irreparable harm.

B. SPD's Likelihood of Success on the Merits

An applicant for a stay of injunction pending appeal must make "a strong showing that he is likely to succeed on the merits." *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987). Generally, this requires showing "a substantial possibility, although less than a likelihood, of success." *Mohammed v. Reno*, 309 F.3d 96, 101 (2d Cir. 2002); *LaRouche v. Kezer*, 20 F.3d 68, 72 (2d Cir. 1994). If the applicant demonstrates that a "serious legal question is involved" in the appeal, a stay is appropriate where there is a "substantial case on the merits" and "the balance of the equities weighs heavily in favor of granting the stay." *LaRouche*, 20 F.3d at 72-73.

SPD raises two issues to demonstrate "a strong showing" that it is "likely to succeed on the merits. First, SPD argues that, after *POM Wonderful LLC v. The Coca-Cola Company*, 134 S. Ct. 2228 (2014), there is a question of first impression in the Second Circuit on whether the FDA's pre-approval of advertising for a medical device precludes Lanham Act false advertising claims. SPD Br. at 12. In addition, SPD argues there is a serious question as to whether C&D was entitled to a "presumption of consumer confusion as to all of SPD's advertising based on . . . intentional deception . . . tied to only specific pieces of advertising." *Id.*

This Court first rejected SPD's FDCA preclusion argument at the motion to dismiss stage. *See Church & Dwight*, 2014 WL 2526965, at *7-*14 (S.D.N.Y. June 3, 2014). Shortly thereafter, the Supreme Court reaffirmed in *POM Wonderful* that the "Lanham Act and the

FDCA complement each other" and that the FDCA does not necessarily preclude Lanham Act claims alleging false or misleading labeling. 134 S. Ct. at 2238-39. In light of this new precedent, the Court reconsidered the preclusion issue at the motion *in limine* stage. *See Church & Dwight Co., Inc. v. SPD Swiss Precision Diagnostics, GmbH*, No. 14-CV-585 (AJN), 2015 WL 2359467 (S.D.N.Y. Mar. 24, 2015). This Court, like other courts to consider the question, determined that while *POM Wonderful* concerned food and beverage labeling, its reasoning applied equally to medical device labelling. *See id.* at *6; *see also Connections, Inc. v. Ivera Med. Corp.*, No. 14-CV-70-TC, 2014 WL 3536573, at *4-*5 (D. Utah July 14, 2014); *JHP Pharm., LLC v. Hospira, Inc.*, 52 F. Supp. 3d 992, 999-1000 (C.D. Cal. 2014). Ultimately, this Court held that *POM Wonderful* "only strengthen[ed] the Court's earlier analysis" on the FDCA preclusion point. *Church & Dwight*, 2015 WL 2359467, at *1 (S.D.N.Y. March 24, 2015); *see also JHP Pharm.*, 52 F. Supp. 3d at 999 (finding *POM Wonderful* to be a "strong holding in favor of Lanham Act claims"). Additionally, after an eight-day bench trial, the Court noted that the trial had "reinforced the Court's prior observation that the Lanham Act and the FDCA complement each other, allowing the expertise, perspective, and resources of market competitors [on the question of consumer confusion] to augment those of the FDA." July 1 Opinion at 45.

SPD intends to raise the preclusion issue again in its appeal. In its argument that the preclusion question is a serious one, SPD points to the only post-*POM Wonderful* case where a district court barred a Lanham Act claim as precluded by the FDCA. *See Catheter Connections,* 2014 WL 3536573. In that case, the allegedly false advertising was that the product did not require FDA approval. *Id.* at *2. Because the false advertising claim "require[d] direct interpretation and application of the FDCA" (as to whether or not the device did, in fact, need FDA approval), the district court held that the claim was precluded. *Id.* at *4. Here, unlike in

Catheter Connections, C&D's false advertising claim does not "require direct interpretation and application of the FDCA," but instead involves fact-intensive questions of consumer confusion. In light of *POM Wonderful*'s "strong holding in favor of Lanham Act claims," *JHP Pharm.*, 52 F. Supp. 3d at 999, SPD does not demonstrate that there is a "serious legal question" as to the FDCA's preclusion of C&D's particular false advertising claim.

As for SPD's other argument, this Court did not rely merely on the presumption of consumer confusion in reaching its conclusions. Instead, the Court explained that C&D "presented evidence that this Court found persuasive of likelihood of consumer confusion based on Mr. Poret's surveys." July 1 Opinion at 36. This independent evidence of consumer confusion undercuts SPD's argument that the presumption of consumer confusion is a "serious legal question" in this case.

Even if there were a "serious legal question" for SPD's appeal, SPD has not demonstrated that "the balance of the equities weighs heavily in favor of granting the stay." *LaRouche*, 20 F.3d at 72-73. To the contrary, SPD's intentional deception in advertising weighs against a stay of an injunction requiring correction of the intentionally false advertising.

C. Substantial Injury to C&D

When evaluating the injury to the non-applicant of granting a stay of injunction, the measure of injury is not irreparable harm, but substantial harm. *LaRouche*, 20 F.3d at 72 (quoting *Hilton v. Braunskill*, 481 U.S. 770, 776 (1987)). SPD argues that C&D will suffer no harm from a stay of injunction because SPD's proposed plan to "place curative sleeves on the packaging . . . would eliminate or mitigate any loss C&D might suffer from any misleading message on existing packaging." SPD Br. at 10. Regardless of whether this Court allowed sleeving instead of a recall, the purpose of the stay is to delay compliance with the injunction.

As a result, SPD would be under no obligation to place sleeves on the packaging and its product would remain on store shelves without corrective labeling for the duration of the stay. Keeping the misleadingly labeled product on store shelves for a longer period prolongs the existing harm that C&D has suffered from SPD's false advertising, another factor weighing against granting the requested stay. This is particularly true in light of the bifurcation of the liability and damages stages of the case, which delays C&D's ability to obtain an alternative form of relief. *See* Dkt. No. 42.

D. Public Interest

"The public interest is served by preventing customer confusion or deception." *Reckitt Benckiser Inc. v. Motomco Ltd.*, 760 F. Supp. 2d. 446, 457 (S.D.N.Y. 2011) (quoting *Osmose, Inc. v. Viance, LLC*, 612 F.3d 1298, 1321 (11th Cir. 2010)). This Court's July 1 Opinion found that SPD had engaged in intentional false advertising. As a result, the packaging for SPD's product currently on shelves in retail locations is misleading. The public interest weighs in favor of removing this misleading advertising as quickly as possible. SPD argues that consumers have an interest in having the Product available to them. But keeping the Product available requires allowing intentionally false advertising material to stay on the shelves; the interest in avoiding consumer confusion and deception outweighs the interest in access to this particular product.

In sum, SPD has failed to demonstrate irreparable harm or a likelihood of success on appeal. In addition, a stay would perpetuate false and misleading advertising, thereby harming C&D and the public. As a result, the Court DENIES SPD's motion to stay the injunction.

III. OTHER REQUESTED RELIEF

A. Sleeving in lieu of Recall

In its July 1 Opinion, this Court indicated it was inclined to order SPD to remove the Product from stores. SPD argues that it should instead be permitted to undertake "sleeving," whereby the problematic packaging is covered with a cardboard sleeve of new packaging. SPD Br. at 14. With a recall, product would have to be removed from stores, repackaged in new boxes, and shipped back to stores. *Id.* With sleeving, however, "repackaging" (i.e. placing sleeves on the boxes) would occur at the retail location. *Id.*

The essential difference between the recall and sleeving appears to be what happens between entry of the injunction and the preparation of new packaging. SPD cannot place any new packaging material on the product until that packaging is approved by the FDA, a process which SPD estimates will take two weeks. Zingg Decl. ¶ 10 (Dkt. No. 401). SPD further estimates that it will take another five to six weeks after FDA clearance to deliver the new packaging to retailers. *Id.* Thus, with the sleeving method, current product would remain on the shelves for at least seven or eight weeks in its current misleading packaging before sleeves are made available. On the other hand, SPD estimates that a recall would begin immediately and could be *completed* within four weeks with all current Product removed from stores. *Id.* ¶ 6.

SPD points out that it has completely ceased shipping the Product in its current packaging. *Id.* ¶ 7. Allowing sleeving, which would take at least seven weeks to complete, would allow SPD to sell out its inventory currently on store shelves, obviating the need for either recall or sleeving. Given the intentional nature of SPD's false advertising and the interest of avoiding consumer confusion, the Product should not be allowed to remain on the shelves for

weeks before steps are initiated to correct false advertising. Thus, this Court concludes that "sleeving" is not an appropriate remedy.

"[A] district court should carefully consider the likely burden and expense of a recall before it imposes the remedy." *Perfect Fit Indus., Inc. v. Acme Quilting Co., Inc.*, 646 F.2d 800, 807 (2d Cir. 1981). The above analysis demonstrates that the main alternative, sleeving, is inadequate in delaying the removal of intentionally false and misleading packaging from store shelves and allowing SPD to sell out its inventory before taking corrective measures. As a result, this Court reaffirms that a recall is appropriate in this case, despite the expense it may impose on SPD. The specific contours of such a recall are set forth in the Court's permanent injunction order issued simultaneously with this Memorandum & Order.

B. Short Stay to Seek Approval of New Packaging from the FDA

In addition to the other relief discussed above, SPD seeks a short stay to seek FDA approval for its new packaging. Any changes to the Product packaging require FDA approval, which SPD estimates will take approximately two weeks. SPD Rep. Br. at 8. This Court is cognizant of the fact that SPD cannot place new packaging on shelves until it is approved by the FDA. However, allowing intentionally false and misleading packaging to remain on store shelves for a longer period of time in order to accommodate SPD's FDA approval schedule is not an appropriate solution. This is particularly true here, where SPD could have taken the weeks since the Court's July 1 Opinion to begin seeking FDA approval, but does not appear to have done so. In crafting the recall timeline in its permanent injunction order, the Court has endeavored to give SPD sufficient time to seek and receive FDA approval for its new packaging, but it will not stay the injunction on that basis.

C. Temporary Stay to Seek a Stay from the Second Circuit

Finally, SPD requests a temporary stay to seek a stay from the Second Circuit. District courts denying a motion to stay an injunction have granted temporary stays for the moving party to file a motion to stay under Rule 8(a) of the Federal Rules of Appellate Procedure. *See, e.g.*, *LNC Invs., Inc. v. Republic of Nicaragua*, No. 96-CV-6360 (JFK), 2000 WL 729216, at *2 (S.D.N.Y. June 6, 2000). Such stays generally remain in effect until the stay motion is decided by the appellate court. *Id.* Granting such an injunction is "an exercise of judicial discretion, and the propriety of its issue is dependent upon the circumstances of the particular case." *Nken v. Holder*, 556 U.S. 418, 433 (2009) (internal quotation marks omitted).

While SPD is entitled to seek a stay from the Second Circuit under Rule 8(a), this Court will not grant a temporary stay for SPD to seek such relief. As noted above, this Court sees SPD's likelihood of success on appeal to be minimal and is concerned with the public interest in having intentionally false and misleading product packaging removed from shelves as quickly as possible. In light of the delay that even a temporary stay could cause in correcting the false and misleading packaging, this Court declines to issue one.

IV. CONCLUSION

For the foregoing reasons, the Court denies Defendant's motion in its entirety. This resolves Dkt. No. 398.

SO ORDERED.

Dated: August 26, 2015
New York, New York

ALISON J. NATHAN
United States District Judge